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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,960	03/27/2000	Michael Friedman	3940/0K188	3862

7278 7590 04/08/2003

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EXAMINER

HOWARD, SHARON LEE

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/08/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/534,960

Applicant(s)

FRIEDMAN ET AL.

Examiner

Sharon L. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/10/02, 12/17/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-93 and 95-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-93 and 95-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Receipt of power to inspect filed on 12/10/02, supplemental prior art with attachment and Preamendment C filed on 12/17/03 have been acknowledged..

Claims 1-46 and 94 have been cancelled.

Claims 47,51,55,59,62,65,68,70,76,82,85,93,96 have been amended.

New claims 95-99 have been added and claims 47-93,95-99 are pending.

The request filed on 12/17/03 for three months extension of time and Request for Continued Examination under 37 CFR 1.114 based on parent Application No. 09/534,960 is acceptable. An action for the request under 1.114 follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47-93,95-97 and newly added claims 98,99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohn (U.S. Patent No. 5,264,206) in view of Friedman (U.S. Patent No. 5,160,737).

Bohn teaches a nail lacquer composition and a method of making said Composition which is known in the art for treating mycoses of the nails (col.1, lines 6-54 col.2, lines 46-68 and col.6, lines), comprising antifungal agents consisting of econazole, miconazole and naftifine hydrochloride (see Abstract, col.3, lines 15-68 and the TABLE at col.6, EXAMPLE 1-6), volatile solvents (col.4, lines 46-68, bridging col.5, lines 1-8), additives which are excipients (col.5, lines 9-16), lanolin derivatives, water

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(col.6, EXAMPLES 7-9), film forming agents which include copolymers of methyl vinyl ether, copolymers of acrylic acid and methacrylic acid (col.2, lines 58-68, bridging col.3, lines 1-11) and keratolytic agents (i.e. urea and salicylic acid)(col.5, lines 17-20).

Bohn does not teach a prolonged effect therapeutic nail varnish composition. However, Friedman discloses a liquid methacrylic acid polymer composition containing sustained-release of pharmacological active agents (see Abstract) which are known in the art for treating dermatological conditions of the skin (col.21, lines 13-34), wherein the active agents comprises fungal, bacterial and viral agents (col.7, lines 8-64), antifungal and an antiviral agent (col.8, lines 42-56), about 1% of a plasticizer, dibutyl phthalate or PEG (col.16, lines 18-27), water, ethyl alcohol (col.9, lines 5-13 and col.11, lines 63-65), clotrimazole, miconazole nitrate, fluconazole, ketoconazole, tolnaftate or nystatin (col.13, lines 34-47), antibacterials (erythromycin, clindamycin, gentamycin, neomycin or tetracycline) and antivirals (acyclovir, amantadine or ribavirin (col.14, lines 4-7). Friedman discloses that the agent is embedded in a sustained-release carrier comprising a hydrophobic acrylic polymer (i.e. methacrylic acid type A copolymer) or an acrylic polymer, in a pharmaceutically acceptable vehicle (col.11, lines 57-61 and col.15, line 33). Friedman also teaches using about 1% of humectants (glycerol, sorbitol or mineral oil (col.16, lines 18-21) and that one skilled in the art would be able to produce the particular amount of each of the agents and the sustained release polymer (col.16, lines 38-40).

It would have been within the skill of the ordinary practitioner at the time the invention was made to use a sustained release composition taught by Friedman which is known in the art for treating conditions of the skin, in a nail varnish composition taught by Bohn et al, with the expectation of achieving a composition for treating conditions of the skin and mycoses of the nails. One would expect to achieve similar results.

The method of making the sustained release composition is an obvious process known in the pharmaceutical art.

Response to Arguments

Applicant's arguments filed 12/17/03 have been fully considered but they are not persuasive. Applicant argues that neither Bohn nor Friedman has a specific teaching of the three necessary ingredients (an antifungal agent, a keratolytic agent and a humectant), nor or how they cooperate in the present invention in an advantageous manner to trap water and maintain it close to the nail and thereby increase the nail permeability which is also enhanced by the keratolytic agent. Bohn does not spell out the functions and effective amounts of particular optional ingredients. Bohn discloses ingredients in the form of "laundry list" without specific direction and without specific teaching or motivation to arrive at the presently claimed invention. There is no hint that water could contribute to the effectiveness of the antifungal formulation.

Applicant also argues that Friedman does not supply the disclosure of the motivation lacking in Bohn. Neither reference requires that a humectant in sufficient quantity to attract water accordingly or water to be necessary in the formulations disclosed. Applicant argues that Friedman fails to mention a fungal nail varnish and

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that Friedman does not provide any motivation to specifically combine an antifungal, keratolytic, and a humectant (and water).

In response to applicants' argument that Bohn nor Friedman have a specific teaching of the three necessary ingredients, Bohn teaches antifungal agents (see the abstract and the Table at col.6), and urea and salicylic acid which are keratolytic agents (col.5, lines 17-20). Friedman teaches a sustained released composition comprising antifungal agents (col.13, lines 34-47) such as clotrimazole, miconazole nitrate, fluconazole, ketoconazole, nystatin and tolnaftate. Friedman teaches a humectant consisting of glycerol and sorbitol (col.16, lines 18-21). The motivation to combine Bohn and Friedman is to include a sustained release composition taught by Friedman in a composition taught by Bohn, with the expectation of achieving a composition for treating mycoses of the nails and conditions of the skin.

In response to applicants' argument of the functional amounts of each ingredient, the ordinary practitioner would be able to determine the particular amounts by routine experimentation. The argument that water increases the permeability of the nail in combination with the keratolytic agent is an intended use which is not critical in determining the patentability of the composition.

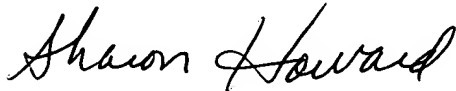
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 746-3121 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Sharon Howard
April 3, 2003



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500